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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/612,314	07/07/2000	Richard Anthony Godwin Smith	088362/0114	8725

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EXAMINER

SAUNDERS, DAVID A

ART UNIT PAPER NUMBER

1644

DATE MAILED: 08/05/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

612,314

Applicant(s)

SMITH et al

Examiner

SAUNDERS

Group Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 4/24/02.
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-26, 28-32, 34, 37, 39, 41-45, 47-48, 50-52 is/are pending in the application.
- Of the above claim(s) 18, 23-25, 29-32, 34, 39, 42-43, 47-48, 50-52 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-17, 19-22, 26, 28, 37, 44, 44 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☒ Claim(s) 1-26, 28-32, 34, 37, 39, 41-45, 47-48, 50-52 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

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Claims 1-26, 28-32, 34, 37, 39, 41-45, 47-48, and 50-52 are pending.

Applicant's election of Group XXIII (Claims 1-24, 26, 28, 37, 41 44, 47 and 50 as they relate membrane soluble polypeptides that are complement inhibitors in Paper No. 12 of 4/24/02) is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 18, 23-24, 47 and 50 are not consistent with a soluble polypeptide that is a complement inhibitor are thus withdrawn.

Applicant is correct in indicating that Group XXIII was incorrectly indicated as XVIII in the restriction requirement.

The following correction has been entered in the Office record.

In the restriction requirement stated at pages 6-9, starting with the Group at page 6 indicated as "IX", all Group number have been increased by a value of five, according to the Roman numeral system.

These changes have been entered in red, and initiated and dated by the examiner.

Applicant is requested to correct his file copy.

The disclosure is objected to because of the following informalities: Applicant's sequence listing, filed on 10/30/01 (Paper 9), though meeting the requirements set forth in the Sequence Letter mailed 9/27/01 (Paper 7), is repletewith misinformation that would never direct one searching these sequences to applicant's invention.

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By way of example, note SEQ I.D. NO: 8 (pages 4-5 of the sequence listing) which shows a 215 mer with a cys-cys at positions 198 and 199. This sequence has been entered into the data base as having a peptide bond between these two residues. In actuality applicant intends this to be a disulfide bond joining two peptides. See notations in the SEQ ID NO listing and see Example 8, at specification page 38. The sequence listing thus fails to set forth applicant's invention. Numerous other sequences (e.g. listing in claim 22) have a like problem. Applicant might consider listing the sequence of Example 8 as two separate sequences and provide notations as to where these are bonded to each other via disulfide bonds.

Appropriate correction is required.

Claim 2 is objected to because of the following informalities: In claim 2 --affinity has-- has been misspelled. Appropriate correction is required.

In claim 12, last line, the "star" superscript should be an "X" superscript.

Claims 1-17, 19-22, 26, 28, 37, 41, and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, last line "exposed to extracellular fluids" is unclear when the claim is read for its embodiment involving "artificial membranes". In such case, what would be extracellular?

In claim 4, "specific membranes" is unclear as to what is specific. Numerous of the disclosed and recited "membrane binding elements" do not appear to be binding with any type of ligand-receptor type "specificity".

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In claim 12 the last Markush group member must be set off by --and-- rather than "or".

Claims 22 and 28 are unclear, because as noted supra in the objection to the specification, the amendment of Paper 9 has rendered the recited SEQ ID NOS as not representative of applicant's invention, by virtue of setting forth a Cys-Cys bond as a peptide bond instead of as a disulfide bond.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-8, 12-13, 19-20, 37, 41, and 44 are rejected under 35 U.S.C. 102(b) or (e) as being anticipated by Ritteshaus et al. (WO 94/26786 or U.S. 5,856,300).

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Rittershaus et al teach a soluble dervative of CR1 linked to one or more carbohydrate ligands such as Lewis-X or sialyl Lewis-X. See especially col. 23 - col. 24 and col. 30 - col. 33 for linking of the carbohydrate ligands.

One would have realized that the recited additive property recited in instant claim 1 would inherently result upon the provision of two or more carbohydrate ligands attached to the sCR1.

The quantitative recitations of claims 2-5 are considered inherent, absent the ability of the USPTO to conduct comparative testing of compositions. Ex parte Gray 10 USPQ2d 1922.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, Ph.D., whose telephone number is (703) 308-3976. The examiner can normally be reached on Monday-Thursday from 8:00 a.m. to 5:30 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christian Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

D. Saunders:jmr

July 25, 2002

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182/1644